

April 2, 2022 with Donna Kimbark, PhD:

Thank you very much for this opportunity. It's great to be able to do this for the bladder cancer community. And as you said, I am the program manager for the PRCRP and I'm going to be taking you through this today. So let's go to the next slide. The agenda today is fairly straightforward. We're going to talk about the history of the PRCRP, the congressional language that goes along with the PRCRP. I'm going to talk to you a little bit about our overarching challenges and program initiatives and what that means for the types of funding opportunities that we offer. I'm also going to talk to you a little bit about some tips for success and some pitfalls that I've seen in the past. So I do want to point out that I will not be covering anything about the congressionally directed medical research programs, which is the umbrella organization within the department of defense that the PRCRP sits under.

If you want more information, I strongly suggest you go to <u>CDMRP.army.mil</u> and look for more information there about the CDMRP. Let's go to the next slide. As an introduction to the PRCRP I just want to tell you a little bit about its history. It began in fiscal year '09 with an appropriation of 16 million dollars. That congressional language directed the different topic areas, we had four at the time, and research areas that might be included as well. From fiscal year '09 to '22 we've had a total of 35 topic areas appear throughout the years under this PRCRP. None of them have appeared all at once. The most that we have ever had in one year or is 20 different topic areas.

From '09 through '21, we've had about 650 million dollars with 920 awards. And for fiscal year '22 we have our largest appropriation yet, 130 million dollars. Our vision is really to advance mission readiness for those in the US military affected by cancer as well as to improve the quality of life by decreasing the burden of cancer on service members, their families, veterans, and the American public. Our mission is to successfully promote high impact cancer research across the entire cancer research spectrum. So let's go to the next slide. The PRCRP has specific congressional language, as I mentioned on that agenda slide. The FY 22 topic areas are shown here. We have 20 different topic areas and right at the top is bladder cancer. So it's really important for you to pay attention to that. The types of topic areas that we have.

Certain types of topic areas that we will not be covering are included on the right hand side of the slide and you really don't need to worry about that right hand side of the slide at all because of the fact at none of these are areas that you're going to be interested in. They don't cover bladder cancer for instance. These are the ones that are prohibited. Bladder cancer is allowed. The one thing that you want to pay attention to is the relevance to service members and their families. But I'll get into that in a moment. So let's go to the next slide. Here is relevance to military health focus areas. When we're talking about relevance to military health, a lot of people ask me, "Well, how is cancer specific to the military?"

We're not saying that it's specific to the military, but we are saying that military health is important to our mission readiness and to the overall force vulnerabilities. So in order to ensure that the US military is always mission ready, we have to make sure that cancer is not going to impact our military health. On the right hand side of that slide you can see some cancer risk factors that have shown to be important in

military health. And it's also important to note that we have two different focus areas that you can cover as answering in the funding opportunities, including environmental and exposure risk factors such as environmental carcinogens that could lead to bladder cancer. We know that there is a possibility that some pesticides may lead to bladder cancer. But gaps in the cancer research spectrum may affect mission readiness as well, such as gaps in cancer prevention, early detection, prognosis, treatment, quality of life and survivorship.

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You can imagine that if a service member has cancer or one of their family have cancer, that service member is no longer going to be mission ready. And if that service member is no longer mission ready, the whole unit is not mission ready, and that causes force vulnerabilities. So keep that in mind as you're thinking about bladder cancer and how you might answer those military health focus areas. Let's go to the next slide. Some selected outcomes that I like to point out for the bladder cancer community is right at the bottom there that symphony is done by Dr. Brant Inman and he is looking at immunotherapy and nanotherapy combined for bladder cancer.

What he's actually doing there is he's using that photodynamic thermal nanotherapy to elicit not only killing off the possible cancer within the bladder but also to elicit immunotherapy response and that immunotherapy response then could then hit the different cancer that is spread throughout the area or to different areas that bladder cancer might metastasize to. So we're really excited about this new innovation and discovery that he's made. We're looking forward for some products to come out of that. Let's go to the next slide. One of the things that we might want to talk about is our overarching challenges. Now you might think that a program like the peer review cancer research program with its 20 different topic areas cannot really have a strategic plan, but I consider that a challenge when you say that to me. And so what we did was, we thought about the cancer capability gaps in each one of the different cancers and in cancers in general.

And when we thought about that, we brought it down and distilled it into 14 different overarching challenges, which are in these six different categories from prevention, diagnosis, treatment, behavioral science, diversity, and resources. Those are our six different categories. But what you must do during your application process is to answer one of the overarching challenges that are shown underneath those six different categories. What you have for instance is developing strategies to address survivorship issues or transform cancer treatment or identifying elucidate mechanisms to improve prevention. So any of these would be what you would be answering during your application. And we think that they're broad enough to cover anything that you might be interested in, but at the same time brings us down and actually focuses some of the research that we're looking for so that it hits those capability gaps that we think are very important for a peer view cancer research program.

Let's go to the next slide. Our strategic plan is shown here. I think it's really important to emphasize that we do have a strategic plan, even though we are a multicancer program. Our initiative number one is convergence and career development. It has been an important part of our complete program from the get-go, from the very early time of our program in the fiscal year '09 that we do career development. And so what we've done, and we've developed this initiative all the way to the Convergent Science Virtual Cancer Center, this Virtual Cancer Center aims to enhance career development with the inclusion of convergent science training to include military health. What is convergent science? Convergent science as defined by the National Science Foundation is a means to solve vexing research problems in particular complex problems.

And when we look at cancer, cancer is one of the most vexing biomedical research problems that we have out there. And one of the things that I want to point out is that it's beyond multidisciplinary

studies. It's really bringing together different expertise from physics and mathematics to life sciences and forming novel frameworks to catalyze scientific discovery and innovation. And that brings us to our next initiative and that's innovation and impact. This is an opportunity to support innovative and impactful ideas as well as enhance support of clinically relevant ideas. So we have two initiatives. Let's go to the next slide. When we look at our two different funding opportunities, categories, convergent science and innovation and impact, we have a couple of different types of funding opportunities under each one of them. In FY 20, we offered the Virtual Cancer Center. It's not being offered in fiscal year '22, but what is being offered in fiscal year '22 is the career development scholar option and it is the scholar award. And this career development award with scholar option is connected to the Virtual Cancer Center.

It gives you an opportunity to be part of that Virtual Cancer Center, which I will detail in a moment. The convergent science cancer consortium development award is a step beyond our investment in the Virtual Cancer Center. So we're very excited about this and I'll detail that in a moment. Other things that we're also doing is the innovation and impact. We're really pushing that career development with a fellow option that is not connected to the Virtual Cancer Center. The idea award, the impact award, the translational team science award and the behavioral health science award. I'll speak on each one of these and how you can apply for each one of these in a moment. Let's go to the next slide. Here is the Virtual Cancer Center, and I wanted to introduce this to you so that you would understand what the scholar is all about. Here is the Virtual Cancer Center. It is a convergent science based Virtual Cancer Center. It is an academy like type of reward mechanism.

If you've ever heard of an academy like type of reward mechanism, these are for independent investigators that are tenure track investigators but they're early on in their career development. All of the ones that you see across the country are currently scholars that are under the Virtual Cancer Center.

The director of our Virtual Cancer Center is Dr. Dan Theodorescu and the deputy director is Dr. Peter Kuhn. Each one of these different scholars have different research strategies and research projects of their own. And they each come from differing backgrounds. We have a psychologist, we have a geneticist, we have a chemist, all of these people are working together, working together and learning how to crosstalk, how to cross pollinate the sciences so that we can attack this vexing problem of cancer and bring it together so that we can understand cancer in a more holistic way instead of a stove-piped way. So that's what the Virtual Cancer Center is about and that's where we're hoping to increase the number of scholars here. Right now we have eight scholars. We would like to bring that up. Let's go to the next slide.

So let's talk little bit about the funding opportunities that are available. The letter of intent is an important part of this process. The letter of intent is simply a letter that says that you intend to apply to the behavioral health science award under bladder cancer. There is nothing else you need to do except to submit that by the submission date for the letter of intent or LOI. No invitation is needed to submit the full application. The behavioral health science award is a one million dollar award in direct costs, indirect costs are over that. It's four years for period of performance. It's for those independent investigators with a faculty level appointment. It really supports research that spans behavioral health science. And we're going to include prevention here, survivorship, quality of life issues that might impinge on the quality of life following cancer diagnosis and treatment. We all know that bladder cancer patients do have issues with their quality of life, as well as survivorship.

So we really want to hit those areas and increase their quality of life. Pilot clinical trials are allowed, but preliminary data is required if you're going to come in with a pilot clinical trial. It must address the FY 22 topic, Gary, which would be bladder cancer here, one of the military health focus areas, and one of the overarching challenges. The translational team science award is 2.5 million dollars in direct costs over a

four year period of performance. Two to three PIs come together at the assistant professor level or above. And what we're looking for is to support translational studies that are associated with an ongoing or completed clinical trial. We all know that a lot of clinical trials cost tons of money, right? And when you have a clinical trial that's costing so much money, you don't usually have enough money for the correlative studies. Here is your chance to get the correlative money.

We are really trying to look at those correlative studies to look at these samples that you've taken, the images that you may have taken. So here we're really wanting to look at that. The clinical trials are allowed here, but they're not the focus of the translational team science award. So you can fund your clinical trial, but it shouldn't be the focus of the translational team science award. Once again, you must address the topic areas, the military health focus areas and the overarching challenges. Just let's go to the next slide. When we look at the next slide here, this is where we go into the career development award. As I told you, career development has been a prime initiative of the PRCRP from the very beginning from fiscal year '09. Here again, it's a letter of intent. You do not need to wait for an invitation submit.

The virtual cancer scholar option is 800K in direct costs. This option is for a fully independent tenured track assistant professors. It's really important to delineate that from our fellow option, and I'll speak to the fellow option in a moment. This is less than seven years from your terminal degree. What that means is, is that from your terminal degree, an MD or PhD, since the time you got that degree until the time of application submission should be less than seven years. We do make exceptions. There are caveats to that. If you had to time off due to medical leave, and that would include COVID, or you had time off for maternity leave, or if you, for instance, had to take care of a family member, or you were in clinical residence or fellowship or something like that, those do not count against that seven years.

What does count against that seven years is postdoctoral time. If you do spend time as a postdoc, it will count against that seven years. This is really to support those scholars to really be interactive and have an in depth intensive mentoring, national networking, and a peer group from the Virtual Cancer Center. We're really trying to set you up for success with the Virtual Cancer Center. You will now already have a collaborative network within the Virtual Cancer Center. Of course you have to address the topic areas, military health focus areas, and the overarching challenges. For the fellow option this is slightly different. This is a 400K in direct cost with a three year period of performance. Here we have independent investigators at the research assistant level or instructor level, the less than seven years all fit in here. The caveats all count as well.

This is really to support really early career investigators that need to get further independent. For instance, you might be a research assistant professor but you might not have your own laboratory itself. You might have laboratory space in an established investigator's laboratory, but that's okay. You just have to be researching and doing your own research and not the research of the established investigator. So that's what we're really looking forward to get you more independent than you are right now and really strengthen that road to independence. Once again, you have the topic areas, military health focus areas and overarching challenges. Let's go to the next slide.

Now since we talked about this scholars quite a bit, now I want to talk about what we're going to do with the convergent science beyond the Virtual Cancer Center. This is once again a letter of intent, no invitation is needed once again, but this convergent science cancer consortium development award, what is it all about? It really is all about putting together a consortium based on convergent science, based on bringing research disciplines that are not usually used within the cancer sphere of influence and bring it into cancer. So we have a coordinating center which would be research site one with topic area one, and then we have research site two which is topic area two, and research site three which is

topic area three. So why do I have so many topic areas? You will have three different topic areas must be answered, three different topic areas, with one unifying overarching challenge.

So for instance, you might have bladder cancer, you might have metastatic cancer, and let's pick a strange one, blood cancer. Okay? You have these three different topic areas that are kind of different. They're not really working together too much. You might work a little bit more with metastatic studies, but probably not too much with blood cancer studies. So we're going to put them together. And now what we're going to do is we're going to have one overarching challenge. And maybe that overarching challenge, for instance, might be behavioral science, where you're looking at quality of life and survivorship issues. And when you're doing that then, what are you looking at? You're looking at survivorship issues for people with metastatic cancer. You're looking at survivorship issues with people with bladder cancer and blood cancer. Now, what can you bring in? What kinds of different sciences can you bring? Maybe bring in a psychologist along with a molecular biologist along with a surgical unit. Who knows? Let's just mix it up and see what we can get out of it.

So we're really supporting novel approaches to ending cancer. We think that this is the next frontier for cancer research. We want to do a proof of principle here. We want proof of principle research projects so that we can say whether or not convergent science is actually the next frontier for cancer development and cancer research. So we're asking you to come in with a proof of principle research project that each one of your research sites can tackle and each one of your topic areas can tackle as well, and then we want to see how you can cross pollinate and talk to one another. So you will address three topic areas, one military health focus area, or two, it doesn't matter. That one doesn't matter as much. And one overarching challenge. So let's go to the next slide. Now, this is where we get to the pre-proposal.

And I've been telling you a letter of intent, a letter of intent, no invitation is required. This is where the invitation is required for the idea award and the impact award. The pre-proposal for the idea award is one page. For the impact award it's two pages. So you have to submit a pre-proposal by May 25th, and then it will be screened by our programmatic panel and then an invitation, if you are invited, to submit a full application will come to you by July 11th. And then following that you'll write your full application. The idea award is 400K of direct costs over a two year period. And why is it so short? Because we see this as our seed mechanism. Really, this is early concept. We do not want preliminary data. Preliminary data is not required. If you submit preliminary data, it will be evaluated so keep that in mind. Independent investigators at a faculty level of appointment are eligible and we support innovative untested high risk, high gain type of research here.

We don't want something that you've been working on your in your laboratory for quite some time, maybe you're known for it in your laboratory. We don't want that. That's not what we're looking for. We're looking for serendipitous type of observations that you've made or results and you want to bring it forward. You want to go beyond that. No clinical trials are allowed for the idea award. It's not enough money anyway, right? So the impact award is one million dollars over a three year period of performance. Here we're looking at assistant professor and above, and we're supporting research projects that have successfully addressed, really get to that near impact. Really get closer to clinical applicability or to the clinic. That's what we're looking for. So clinical trials are allowed here.

You will need preliminary data in the impact award because these should be mature projects. This is where you're going to the next step. This is where you can say I've been working on this in my laboratory for the last eight years and now we're ready to go to the next translational applied step. That's the impact award. If you don't have that type of information and data for the impact award, you should be applying to the idea award. In the idea award if you're too far along you should be applying to the impact award. Keep that in mind. Once again, clinical trials are allowed here. And for both of these, you

must answer and address topic areas, military health focus areas, and an overarching challenge. So let's go to the next slide. So these are some dates to remember for the behavioral health, for the career development, that should say fellow option and not scholar option in the second career development, and the translational team science award, all of these LOIs or a letter of intent are due by the 12th of July.

They're not needed, you don't need an invitation to submit. You do have to put in the letter of intent, but you don't need an invitation to submit. The full application is due on the 2nd of August. You might say, "Well, that's not a lot of time between July 12th and August 2nd," that doesn't matter. You just have to remember put a reminder on your calendar I'm going to put in a letter of intent on the 12th of July while I'm writing all the way from now until the second, and then you're going to submit. Convergent science cancer consortium development award is an LOI as well. It's due on the 17th of August. You don't need an invitation to submit and the full application as due on the 7th of September. The idea and impact award are both pre-proposals and that's due on the 25th of May. So it's important for you to get moving on that. The invitation to submit will come out the 11th of July and the full application is the 7th of September. So let's go to the next slide.

So some strategies for success, I'm going to hit on some bullet points here that I think are really important that I've seen trip up people along the way. Those deadlines that I just spoke to you about, critical, really important. You're going to say, "Well, I don't really remember them and I want to listen to your whole thing again, so what can I do?" Don't worry about it. Go to the front page of the program announcement or funding opportunity that you're interested in and those deadline dates should be there. Coordinate your efforts, bring the entire team together and justify how and why you can achieve the anticipated outcomes. That's real important to bring this together. Your grantsmanship is critical. Do not tire out the reviewers. If you are going to have multiple abbreviations in a sentence, maybe think about changing that up and doing something so that you don't have those multiple abbreviations in a sentence.

It's really important because of the fact that tired reviewers have a tendency, not to be very happy with your application. You want them to say, "This was a pleasure to read." You don't want them to say, "I haven't a clue as to what these people were doing." So that's important as well. If you can advance the slides a little bit further to the tips for success. There you go. One of the things I like to tell people is, as you're reading the program announcement, I know a lot of it is tiresome to read, but you're going to be looking at the award intent, which is really important for you to pay attention to, but also you're going to go ahead and you're going to look at the application package, which you're required to submit. That's great. But while you're writing, also go back to the back part of the program announcement and look at the peer review criteria and use that as your checklist. Make sure that you fill out everything that the peer reviewers will actually be looking for.

Now, we've tried to mirror them so that there's not a problem there for you to do that, but if you miss out adding in an alternative strategy, the peer reviewers are going to clue in on that because there's a question there about that, and then what they're going to go ahead and say is, they're going to go ahead and say, "You have a weakness here," and you don't want to open up the door for any weaknesses. I'd tell you to put your bottom line up front, that's your Ted Talk, really put it up front and then really make sure that you can back it up. And back up why your research aligns with the intent of the idea award mechanism and that it's innovative and that it's not the next logical step in your research. And the same thing with all of the rest of the different funding opportunities.

When we look at science overall, really all of us are scientists and cool science is good, right, but impactful science is great. If we can help people along I think that that's the most important thing to pay attention to. And I also want to really strongly suggest you use plain language in the lay abstract and the

impact statement, because you will be evaluated this year on that. I've added that into the application presentation criteria so it's really important that you pay attention to using plain language so our patient advocates can read this because they are part of our peer review and programmatic review process. So let's go to the next slide.

Some pitfalls to avoid, do not include the programmatic panel members for the program in the fiscal year to which you are applying. The programmatic panel members are on the right side of this slide. Go through and make sure that they are not part of your research team and you are not collaborating with them on this research. You can have collaborated with them in the past, that's fine, but not on this award, not on this application. Don't exceed the page limits and make sure that you check your files after you've created a PDF version. Don't miss the submission deadlines. We give you the submission deadlines for a reason. And also it's really important that you try to submit a little bit early because between the submission deadline and the grants.gov deadline you have what's called the verification deadline. The grants.gov deadline, as soon as you submit to grants.gov, it will take up to 72 hours for grants.gov to validate your submission.

And it takes us a while to pull them into what we call eBRAP. eBRAP is our portal that you can now go into during the verification period and go and look at each one of your application pieces and make sure that those attachments are correct and that you have submitted the correct biosketch and so on. If you don't, if you do it at the ninth hour, the 12th hour I should say, you do it at the 12th hour for grants.gov, you submit and it takes 72 hours for the grants.gov to validate, now you've lost three days essentially of your verification period which is between five and seven days. You don't want that to happen to you. You want to be able to use your verification period so that you can make sure that everything is correct.

Do not ignore that verification period and submit the correct project narrative and budget prior to the grants.gov deadline, because you cannot change the project narrative or the budget during the verification period. Let's go to the next slide. Some common questions that I get, I'm not from the US can I still apply? Yes, you will need to register with Sam and see the general application instructions on how to do that. When are the due dates? The due dates I already talked about, but they are on the front cover of every funding opportunity. Can a postdoc apply to the career development award? No, the career development award for both the scholar and fellow options require a degree of independence. You can be a research assistant professor or instructor for the fellow option. The scholar option requires you to be a tenured track assistant professor or above.

How is the bladder cancer relevant to military? You can access information on bladder cancer in the military on our webpage. So just go to your favorite browser, put CDMRP, C-D-M-R-P into your into your favorite browser. It'll pop up and then go ahead and click on the research programs. Look for peer review cancer research program, and then you can scroll down and you'll see some information there about exposures and cancer. And that will give you a nice start for looking at bladder cancer relevance to the military. Where do I apply? Start your application on eBRAP.org. That's our portal. You'll start your application, you can put your letter of intent in there and your pre-proposal in there for the different award mechanisms. When you want to submit your full application you will go to grants.gov and you will submit it via grants.gov.

To find the funding opportunities you can go to CDRP.army.mil or grants.gov and put the listing number of 12.420 in to find the PRCRP. Can we get a copy of this briefing? Yes. I'm sure that we will be able to provide it for you. That's why it's in PDF form. Let's go to the next slide. Any more information that you might like to have, go right ahead to the CDMRP website and look for the PRCRP. If there's any questions, I'm sure that Stephanie Chisolm (<u>schisolm@bcan.org</u>) can send them to me. I would be more than pleased to answer any of your questions. And have a good day and good luck.